PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of: MULCAIRE-JONES, George) Group Art Unit: 3736	
•) Examiner: HOEKSTRA, Jeffrey Gerben	
Serial No.: 10/783,647) RULE 132 DECLARATION OF	
Filed: February 20, 2004	j	
Confirmation No.: 7353) Robert Scanlon, M.D. (37 C.F.R. §1.132)	
Communation 140 7555)	
Atty. File No.: 50221-00002)	
For: "APPARATUS AND METHOD OF		
FERTILITY AWARENESS"	?	
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Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir or Madam:

- I. Dr. Robert Scanlon, residing at Z9 Msyle, D., declare as follows:
- 1. I am a board certified obstetrician/gynecologist in private practice in Huntington, New York. As a part of my professional practice, I provide education and support for patients interested in natural family planning. The Curriculum Vitae included as Exhibit A to this declaration summarizes my qualifications and experience.
- Based upon my qualifications and experience, I consider myself one skilled in the art of fertility awareness.
- 3. I have reviewed and considered the above-referenced pending application, including the pending claims, an Office Action dated December 9, 2008 issued by the United States Patent and Trademark Office (the "Office Action") and U.S. Patent No. 6,747,917 issued to Jennings et al. (hereafter "Jennings") and relied upon by the Patent Examiner in the Office Action to reject the pending Claims.
- 4. Based upon my review, I have observed there are substantial differences between the Jennings method and the Mulcaire-Jones method. Specifically, I would note the following:

- The Jennings device is a fixed calendar-day method while the Mulcaire-Jones method is based upon observations and recordings of cervical mucus and dryness.
- Jennings specifically teaches its device is only to be used for women with regular cycles from 26 to 32 days and is not to be used for women with irregular cycles, those who are breast feeding and may not experience a cycle, and those who have cycle lengths outside the 26 to 32 day range.
- The claimed invention advantages, among others, are the ability to record differing daily observations and variations for such things as menstrual bleeding, cervical mucus and dryness. Thus, a woman using the claimed invention must know how to observe biological markers during menstrual cycles that can vary from month to month. Each menstrual cycle is recorded anew by positioning the appropriate bead to match the daily observation. This is accomplished through the use of a plurality of unique and distinct beads (many more than in Jennings) with various shapes, colors and sizes, some of which are also considered his-markers.
- The claimed invention allows for use of a bio-marker in the form of observing and recording of the LH surge detected by an ovulation prediction kit.
- Unlike the Jenning's device, when the woman's monthly cycle is over for those using the
 claimed invention, the beads are removed from their current position and are ready for a
 new cycle to begin, which can become a totally different configuration depending on
 daily observations.
- Unlike the Jennings device, the claimed invention relies on a number of bio-markers for tracking the fertile and infertile phases of a woman cycle. Meanwhile, the user of the Jennings device simply records calcular days on a pre-figured set of beads in which sets of identical beads in size, color and shape are arranged adjacent to each other in predetermined clusters that represent periods of fertility or infertility based upon statistical probabilities. While easily taught and understood, the user does not have to be schooled in the biological specifics of a menstrual cycle. Jennings may work for a majority of women with regular and normal cycles, but for a particular woman at a particular time Jennings may not, in fact, be accurate. The claimed invention fills this void with additional accuracy and confidence.
 - 5. Based upon my review, I conclude that no reasonable rationale exists for one skilled in the art of fertility awareness to modify Jennings to conform to the claimed invention because Jennings specifically teaches only the use of calendar days and does not provide any means to observe, interpret or record variations in bleeding, cervical mucus, dryness or an LH surge. Unlike Jennings, the claimed invention does not rely on a pre-figured constellation of beads in designated sets, but rather requires a woman to create a new, daily record of her menstrual cycle by positioning on a string a specific bead selected and based upon a specific observation for each day of her cycle.
- 6. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true. I understand that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. §1001) and may jeopardize the validity of this patent application or any patent issuing thereon.

Date: _	5/11/09	_ By: _	Rob-t-Scal
			Pohart Scanlon M

Robert Scanion, M.L.

EXHIBIT A

Curriculum Vitae

Robert F. Scanlon Jr., MD 29 Mayfair Drive Huntington, New York 11743

Education

Bucknell University BS Civil Engineering 1978.

Duke University MBA 1981

Allied Chemical Fellowship

Wake Forest University MD 1988

School President 1987

Post Graduate Training

Honors

University Hospital, Rotating Internship 1988-89 SUNY Stony Brook OB/Gyn Residency 1989-92

> Chief Resident 1992-93 Resident of the Year 1993

AOA Inductee 1989

Professional Activity

Sperry Rand Corporation Design Engineer 1978-79

Chemical Bank Loan Officer 1981-83

North Shore Medical Group Physician 1994-present

Life Center of Long Island Medical Director 1998-present

Board Member 2000-present

Aiding Infants and Mothers President 2002-present

Maternal Life International Maternal Health Director
Board Member 2006-present

Creighton Model Medical Consultant Completed training in the Creighton Natural Family Planning method 2008

Research Interests

University Hospital, SUNY Stony Brook Epidural use in Labor, 1993 First Place Resident Research HPV-Colposcopy, 1992 First Place Resident Research

Currently

Maternal Health Issues in the Developing World

NaPro Technology Application of Creighton Model NFP for the Treatment of medical problems

Personal

Married with three children